DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1090B

BUFFALO DISTRICT
Food and Drug Administration
599 Delaware Avenue
Buffalo, NY 14202

13 January 1997

WARNING LETTER BUF 97-10

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

David Verity, President
Mohawk Valley Homecare, Inc.
c/o First Community Care
210 John Glenn Dr., Suite 12
Amherst, New York 14228

Dear Mr. Verity:

An inspection of your liquid oxygen manufacturing facility at 430 Court St., Utica, New York, was performed on 19, 20 and 23 December 1996 by Food and Drug Administration (FDA) Investigator Russ E. Davis. The inspection revealed serious violations of the Federal Food, Drug and Cosmetic Act (the Act) and regulations promulgated thereunder. At the conclusion of the inspection, Carol A. Canter, Branch Manager, was presented with a written list (FDA-483) of objectionable conditions and practices. A copy is enclosed for your reference.

Your product, Liquid Oxygen USP, is adulterated within the meaning of section 501(a)(2)(B) of the Act because the controls used for the manufacture, processing, packing or holding of this product are not in conformance with current Good Manufacturing Practice regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 and 211) such as:

- **The employee responsible for witnessing the strength and purity testing performed by the supplier on each Liquid Oxygen USP home cryogenic unit has not received training specific to the analytical methodology utilized by the supplier [21 CFR 211.25].** Your Service Technician is not trained in the procedures for proper calibration and operation of the [redacted]utilized for Liquid Oxygen USP testing by [redacted].

-Failure to have adequate written procedures describing: the third party (supplier) filling of Liquid Oxygen USP into home cryogenic units; the pre and post-fill checks of home cryogenic units; the testing of home cryogenic units of Liquid Oxygen USP; the distribution of home cryogenic units of Liquid Oxygen USP; and the correct labels and labeling used for Liquid Oxygen USP home cryogenic units [21 CFR 211.100(a), 211.150, and 211.130]. The current written procedures for Liquid Oxygen USP operations do not accurately describe the operations of the Utica, NY Branch.

- Failure to document pre and post-fill visual checks performed on Liquid Oxygen USP home cryogenic units [21 CFR 211.188(b)].

- Failure to document, by signature and date, the review of Liquid Oxygen USP production records for accuracy and completeness [21 CFR 211.188(a)].

In addition, your product Liquid Oxygen USP is misbranded within the meaning of Section 502 of the Act, because it was manufactured in an establishment not duly registered under Section 510 of the Act [Section 502(o); 21 CFR 207.20]; the labeling of the home cryogenic units does not bear the name and place of business of the manufacturer [Section 502(a) & 502(b)(1); 21 CFR 201.1]; does not bear an accurate statement of the quantity of contents [Section 502(b)(2); 21 CFR 201.51]; and, does not bear the required prescription legend [Section 502(f)(1); 21 CFR 201.100(c)].

It is your responsibility to insure all drugs manufactured and distributed by your firm meet the requirements of the Act, and regulations promulgated thereunder. You should take prompt action to correct these and all violations existing at your firm. Failure to take such action may result in regulatory action, such as seizure and/or injunction, **without further notice.**

Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering awarding of contracts. By copy of this letter, we are specifically advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of State or Federal law.

If, after reviewing this Warning Letter and the COMPRESSED MEDICAL GASES GUIDELINE (copy enclosed), you still have questions regarding acceptable methods for complying with these requirements, you may contact Joseph H. Erdmann at our Syracuse Office (315-448-7601).

Please notify this office in writing, within 15 days, of the specific steps you have taken to correct the noted violations and to prevent a recurrence of similar violations. Your response may be directed to Joseph H. Erdmann, Team Leader, P.O. Box 7197, Syracuse, N.Y. 13261.

Sincerely,

Robert L. Hart

Robert L. Hart
Acting District Director

Attachments: FDA-483
Compressed Medical Gases Guideline

cc: Carol A. Canter, Branch Manager
Mohawk Valley Homecare, Inc.
430 Court St.
Utica, NY 13502